

CLAIMS

1. A method of diagnosing CML or a predisposition to developing CML in a subject, comprising determining a level of expression of a CML-associated gene in a patient derived biological sample, wherein an increase or decrease of said level compared to a
5 normal control level of said gene indicates that said subject suffers from or is at risk of developing CML.
2. The method of claim 1, wherein said CML-associated gene is selected from the group consisting of CML 1-190, wherein an increase in said level compared to a normal control level indicates said subject suffers from or is at risk of developing CML.
- 10 3. The method of claim 1, wherein said increase is at least 10% greater than said normal control level.
4. The method of claim 1, wherein said CML -associated gene is selected from the group consisting of CML 191-296, wherein a decrease in said level compared to a normal control level indicates said subject suffers from or is at risk of developing CML.
- 15 5. The method of claim 4, wherein said decrease is at least 10% lower than said normal control level.
6. The method of claim 1, wherein said method further comprises determining said level of expression of a plurality of CML-associated genes.
7. The method of claim 1, wherein the expression level is determined by any one method
20 select from group consisting of:
(a) detecting the mRNA of the CML-associated genes,
(b) detecting the protein encoded by the CML-associated genes, and
(c) detecting the biological activity of the protein encoded by the CML-associated genes,
8. The method of claim 1, wherein said level of expression is determined by detecting
25 hybridization of a CML-associated gene probe to a gene transcript of said patient-derived biological sample.
9. The method of claim 1, wherein said hybridization step is carried out on a DNA array
10. The method of claim 1, wherein said biological sample comprises a mononuclear cell.
11. The method of claim 1, wherein said biological sample comprises a myeloid cell.

- 53 -

12. The method of claim 8, wherein said biological sample comprises a lymphoid cell.
13. A CML reference expression profile, comprising a pattern of gene expression of two or more genes selected from the group consisting of CML 1-296.
14. A CML reference expression profile, comprising a pattern of gene expression of two or
5 more genes selected from the group consisting of CML 1-190.
15. A CML reference expression profile, comprising a pattern of gene expression of two or more genes selected from the group consisting of CML 191-296.
16. A method of screening for a compound for treating or preventing CML, said method comprising the steps of:
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 - a) contacting a test compound with a polypeptide encoded by CML1-296;
 - b) detecting the binding activity between the polypeptide and the test compound; and
 - c) selecting a compound that binds to the polypeptide.
17. A method of screening for a compound for treating or preventing CML, said method comprising the steps of:
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 - a) contacting a candidate compound with a cell expressing one or more marker genes, wherein the one or more marker genes is selected from the group consisting of CML1-296; and
 - b) selecting a compound that reduces the expression level of one or more marker genes selected from the group consisting of CML 1-190, or elevates the expression level of
20 one or more marker genes selected from the group consisting of CML 191-296.
18. A method of screening for a compound for treating or preventing CML, said method comprising the steps of:
 - a) contacting a test compound with a polypeptide encoded by selected from the group consisting of CML 1-296;
 - 25 b) detecting the biological activity of the polypeptide of step (a); and
 - c) selecting a compound that suppresses the biological activity of the polypeptide encoded by CML 1-190 in comparison with the biological activity detected in the absence of the test compound, or enhances the biological activity of the polypeptide encoded by CML 191-296 in comparison with the biological activity detected in the absence of the test
30 compound.

- 54 -

19. The method of claim 17, wherein said test cell comprises a cell obtained from peripheral blood of CML patient.
20. A method of screening for compound for treating or preventing CML, said method comprising the steps of:
 - 5 a) contacting a candidate compound with a cell into which a vector comprising the transcriptional regulatory region of one or more marker genes and a reporter gene that is expressed under the control of the transcriptional regulatory region has been introduced, wherein the one or more marker genes are selected from the group consisting of CML 1-296
 - 10 b) measuring the activity of said reporter gene; and
 - c) selecting a compound that reduces the expression level of said reporter gene when said marker gene is an up-regulated marker gene selected from the group consisting of CML 1-190 or that enhances the expression level of said reporter gene when said marker gene is a down-regulated marker gene selected from the group consisting of
15 CML 191-296, as compared to a control.
21. A kit comprising a detection reagent which binds to two or more nucleic acid sequences selected from the group consisting of CML 1-296.
22. An array comprising a nucleic acid which binds to two or more nucleic acid sequences selected from the group consisting of CML 1-296.
- 20 23. A method of treating or preventing CML in a subject comprising administering to said subject an antisense composition, said composition comprising a nucleotide sequence complementary to a coding sequence selected from the group consisting of CML 1-190.
24. A method of treating or preventing CML in a subject comprising administering to said subject a siRNA composition, wherein said composition reduces the expression of a
25 nucleic acid sequence selected from the group consisting of CML 1-190.
25. A method for treating or preventing CML in a subject comprising the step of administering to said subject a pharmaceutically effective amount of an antibody or fragment thereof that binds to a protein encoded by any one gene selected from the group consisting of CML 1-190.
- 30 26. A method of treating or preventing CML in a subject comprising administering to said

- 55 -

subject a vaccine comprising a polypeptide encoded by a nucleic acid selected from the group consisting of CML 1-190 or an immunologically active fragment of said polypeptide, or a polynucleotide encoding the polypeptide.

- 5 27. A method of treating or preventing CML in a subject comprising administering to said subject a compound that increases the expression or activity of CML191-296.
28. A method for treating or preventing CML in a subject, said method comprising the step of administering a compound that is obtained by the method according to any one of claims 16-20.
- 10 29. A method of treating or preventing CML in a subject comprising administering to said subject a pharmaceutically effective amount of polynucleotide select from group consisting of CML 191-296, or polypeptide encoded by thereof.
30. A composition for treating or preventing CML, said composition comprising a pharmaceutically effective amount of an antisense polynucleotide or small interfering RNA against a polynucleotide select from group consisting of CML 1-190.
- 15 31. A composition for treating or preventing CML, said composition comprising a pharmaceutically effective amount of an antibody or fragment thereof that binds to a protein encoded by any one gene selected from the group consisting of CML 1-190.
32. A composition for treating or preventing CML, said composition comprising a pharmaceutically effective amount of the compound selected by the method of any one of claims 16-20 as an active ingredient, and a pharmaceutically acceptable carrier.
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